REMARKS

This is in response to the Office Action mailed February 13, 2007. Claims 64-65, 67, 69, 70, 76-77, 79, 81-82, 87-88, 90 and 93 have been amended. New claims 98-109 have been added. Support for the amendments to the claims can be found throughout the originally filed application, as indicated below. No new matter is introduced. These amendments do not narrow the scope of the claims but rather clarify certain embodiments. Applicants reserve the right to pursue cancelled subject matter in a continuation application.

Independent claim 64 and its dependent claims 65-75 and 98, independent claim 76 and its dependent claim 77-86, 99 and 101-109, and independent claim 87 and its dependent claim 88-97 and 100 are currently pending and at issue.

35 U.S.C. § 112

Claims 69-70, 76-82, 84-86, 90-91 and 93 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse.

Specifically, the Examiner has rejected dependent claims 69 and 70, asserting that the specification teaches broadly graft polymerized coating monomers can be chosen that (a) comprise functional groups to attach or bind physiologically or pharmacologically active agents or (b) comprise a drug depot permitting the delivery of drugs from the graft polymer coating, respectively, but does not teach that acrylamide and/or N,N-dimethylacrylamide from independent claim 64 are used for these purposes.

New claim 98 has been added based on independent claim 64 to clarify that the invention further comprising at least one crossing-linking agent or at least one monomer substituted with functional groups. These features are set forth and described throughout the specification, e.g., paragraphs 49 and 51. Moreover, cross-linking agents and monomers with functional groups are specifically used in conjunction with the claimed substrates and monomers of claim 64, e.g., examples 1 and 2.

As described in the specification, e.g., paragraphs 49, 51 and 52, applications of using cross-linking agents and monomers with functional groups are to attach physiologically or pharmacologically active agents, to employ the graft polymers as a tie coat for other coatings, and/or to create a reservoir so that materials, such as drugs, can be entrapped in the graft layer and can be leached out when placed in most environments.

Claim 67 has been amended to depend from claim 98. Support for this amendment can be found in the specification, e.g., paragraph 51 and Example 3.

Claims 69 and 70 have been amended to depend from claim 98. Support for these amendments can be found in the specification, e.g., paragraph 51 and 52 and Example 2.

The Examiner has rejected claim 76, asserting that the specification does not teach that the graft polymerized coating is formed of pyridine or piperidene. Claim 76 has been amend to replace the terms "pyridine" and "piperidene" with polyvinylpyridine, 2- and 4-vinylpyridine; 4- and 2-methyl-5-vinylpyridine; N-methyl-4-vinylpiperidine. Support for these amendments can be found throughout the specification, e.g., paragraphs 37 and 47.

The Examiner has rejected dependent claims 79, 81 and 82, asserting that the specification teaches broadly that graft polymerized coating monomers can be chosen (a)

to act as a tie coat to adhere an additional layer to the substrate, (b) that comprise functional groups to attach or bind physiologically or pharmacologically active agent or (c) that comprise a drug depot permitting the delivery of drugs from the graft polymer coating, respectively, but does not teach that monomers recited in independent claim 76 are used for these purposes.

New claim 99 has been added based on independent claim 76 to clarify that the invention further comprising at least one crossing-linking agent or at least one monomer substituted with functional groups. These features are set forth and described throughout the specification, e.g., paragraphs 49 and 51. Moreover, cross-linking agents and monomers with functional groups are specifically used in conjunction with the claimed substrates and monomers of claim 76, e.g., examples 1 and 2.

As described in the specification, e.g., paragraphs 49, 51 and 52, applications of using cross-linking agents and monomers with functional groups are to attach physiologically or pharmacologically active agents, to employ the graft polymers as a tie coat for other coatings, and to create a reservoir so that materials, such as drugs, can be entrapped in the graft layer and can be leached out when placed in most environments.

Claim 79 has been amended to depend from claim 99. Support for this amendment can be found in the specification, e.g., paragraph 51 and Example 3.

Claims 81 and 82 have been amended to depend from claim 99. Support for these amendments can be found in the specification, e.g., paragraph 51 and 52 and Example 2.

New dependent claims 101-109 have been added to further define the cross-linking agent, the monomer with functional groups and the active agent or drug. Support

for these amendments can be found throughout the originally filed specification, e.g., Examples 1-3 and paragraphs 49-52.

The Examiner has rejected dependent claims 90 and 93, asserting that the specification teaches broadly that graft polymerized coating monomers can be chosen (a) to act as a tie coat to adhere an additional layer to the substrate, or (b) that comprise functional groups to attach or bind physiologically or pharmacologically active agent, respectively, but does not teach that monomers recited in independent claim 87 are used for these purposes.

New claim 100 has been added based on independent claim 87 to clarify that the invention further comprising at least one crossing-linking agent or at least one monomer substituted with functional groups. These features are set forth and described throughout the specification, e.g., paragraphs 49 and 51. Moreover, cross-linking agents and monomers with functional groups are specifically used in conjunction with the claimed substrates and monomers of claim 76, e.g., examples 1 and 2.

As described in the specification, e.g., paragraphs 49, 51 and 52, applications of using cross-linking agents and monomers with functional groups are to attach physiologically or pharmacologically active agents or to employ the graft polymers as a tie coat for other coatings.

Claim 90 has been amended to depend from claim 100. Support for this amendment can be found throughout the specification, e.g., paragraph 51 and Example 3.

Claim 93 has been amended to depend from claim 100. Support for this amendment can be found throughout the specification, e.g., paragraph 51 and 52 and Example 2.

The addition of claims 98, 99 and 100, and amendments to claims 69, 76, 79, 81, 82, 90 and 93 should obviate all of the Examiner's 112 rejections. The Applicants respectfully request these rejections be withdrawn.

35 U.S.C. § 102

Claims 64-70 and 71-79 were rejected under 35 U.S.C. § 102(e) as being anticipated by Michal (U.S. Patent No. 6,287,285). Applicants respectfully traverse.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131 (quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). In order to anticipate, the elements of the prior art must be present and arranged as required by the claim. § 2131.

On page 6 of the Office Action, the Examiner asserts that the broadest reasonable interpretation of the term "substrate" is not limited to one material or one layer of material and that the substrate is defined merely as an object or article in which layers of material are applied. The Examiner concludes that the scope of the term substrate would include multi-layered objects or articles, including substrates that comprise coatings.

On page 15 of the Office Action, the Examiner reiterates his broader interpretation of the term "substrate" and contends that the term is not given a specific definition by applicant in the specification, and so the Examiner concludes that it must be given its broadest interpretation. The Examiner argues that this interpretation of the term "substrate" would include articles such as desks, which would include many different materials, layers, coatings, etc., and would include a medical device and base coat.

Applicants disagree with the Examiner's interpretation. The term "substrate" is used in the claims and specification, e.g., paragraphs 11, 14, 17, 18, 21, 36 and 37, as meaning the article or material that forms the body of the medical device and not as encompassing an article and a coating. In fact, the specification and claims are consistent when referring to the substrate and the coating as separate features.

The specification specifically refers to the substrate consistent with the Applicants' interpretation of the substrate as an article (e.g., the body of the device) and not as an article and coating, e.g.,

> The substrate can be of any suitable form or shape, including but not limited to tubing, sheets, fibers, strips, films, plates, filaments, pellet resins, powders, and *extruded, molded or cast articles*. Optionally, the substrate can comprise a medical device, including but not limited to catheters and drains. The substrate can be hydrophobic or hydrophilic.

Paragraph 27 (emphasis added). Nowhere in the specification is the substrate referred to or interpreted to mean an article (e.g., the body of the device) and a coating. Based on how the term substrate is defined and used throughout the application and claims, it would be unreasonable to interpret the term as including "articles such as desks, which would include many different materials, layers, coatings, etc." or as including "the combination of a medical device and base coat".

With the Examiner's broad interpretation of the term "substrate", independent claim 64 was rejected based on Michal. The Examiner asserts that the combined metal device and the base coat over top of the metal device taught in Michal constitute a substrate. The Examiner further asserts that the base coat may comprise copolymers of polyurethane and that a top coat may be added which comprises a monomer of acrylamide or dimethylacrylamide.

As discussed above, the term "substrate" as used and defined throughout the specification and claims, does not include a substrate (the device body) and a coating, as broadly interpreted by the Examiner. However, to expedite prosecution of the application, claim 64 has been amended to define the substrate as an insertable medical instrument formed from polymers or copolymers selected from the group consisting of polyurethane and silicon.

Michal does not teach, disclose or suggest all the elements of the present claims, e.g., a substrate, as used in present claim 64, formed from polymers or copolymers selected from the group consisting of polyurethane and silicon.

Furthermore, claims 65-75 and 98 all depend, either directly or indirectly, from claim 64, and thus incorporate all of its elements. Therefore, claims 65-75 and 98 are also patentably distinguished from Michal as set forth above. Accordingly, Applicants respectfully request that the rejection of claims 64-75 and 98 over Michal be withdrawn.

The Examiner has rejected independent claims 76 and 87 over Michal, asserting that in one embodiment, Michal discloses a substrate comprising polymers or copolymers of polyolefins or polyamides (col. 5, l. 34-41), and in another embodiment, discloses a base coat and a top coat, wherein the base coat comprises a monomer such as methacrylate (col. 8, l. 28-31 and l. 50-54).

Applicants disagree with the Examiner's characterization of Michal. Michal does not teach, disclose or suggest all the elements as arranged and required by the present claims. The Examiner appears to be fishing through Michal to identify features of the present claims. However, Michal, if characterized appropriately, is not an enabling reference to reject the claims. However, to expedite prosecution of the application, the

terms polyolefins and polyamides have been removed from claims 76 and 87. Applicants reserve the right to file a continuation application on any cancelled subject matter.

Michal does not teach, disclose or suggest all of the elements of the present claims, as set forth in present claims 76 and 87, e.g., a substrate formed from polymers or copolymers selected from the group consisting of polyurethanes, silicones and latex, or polyurethanes, silicon polymers, polyvinylchloride and latex, respectively.

Furthermore, claims 77-86, 99 and 101-109 and claims 88-97 and 100 all depend, either directly or indirectly, from claims 76 and 87, respectively, and thus incorporate all of their elements. Therefore, claims 77-86, 99 and 101-109 and claims 88-97 and 100 are also patentably distinguished from Michal as set forth above. Accordingly, Applicants respectfully request that the rejection of claims 76-109 over Michal be withdrawn.

35 U.S.C. § 103

Claim 71 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Michal (U.S. Patent No. 6,287,285) in view of Goldberg (U.S. Patent No. 5,804,263). Applicants respectfully traverse.

Applicant contends that the Examiner has not established a *prima facie* case of obviousness as set forth in MPEP §§ 706.02(j) and 2143, because there is no motivation to combine the references.

Claim 71 is a dependent claim based on claim 64. As discussed above, claim 64 is novel and not obvious over Michal. Claim 71 is also novel and not obvious because Michal does not teach, disclose or suggest all the elements of the claim, e.g., a substrate formed from polymers or copolymers of silicon.

Moreover, one skilled in the art would not be motivated to combine the teaching of Michal with Goldberg, because Goldberg teaches away from Michal.

Michal discloses and requires a binding component and a grafting component polymerized and *crosslinked* to the binding component (e.g., throughout specification and claim 1).

Goldberg discloses methods and materials with modified surfaces using gamma-irradiation or electron beam irradiation induced polymerization (e.g., throughout specification and claim 1). Goldberg teaches away from other methods of surface grafting of hydrophilic monomers onto hydrophobic polymers for a variety of reasons, e.g., because of the relatively high penetration power of the radiation required for grafting, permanent chemical and structural changes such as *cross-linking* and degradation are commonly encountered (col. 1, l. 66 to col. 2, l. 17).

Because Goldberg teaches away from the disclosure of Michal, one skilled in the art would not be motivated to combine the two teachings.

Accordingly, Applicants respectfully request that the rejection of claim 71 over Michal and Goldberg be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of

Allowance indicating the allowability of claims 64-109 and that the application be passed to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

We believe that no additional fees are due. However, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 22-0261, under Order No. 32286-232713.

Respectfully submitted,

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Zayd Alathari
Registration No. 42,256
VENABLE LLP
P.O. Box 34385
Washington, D.C. 20043-9998
Telephone: (202) 344-4000
Telefax: (202) 344-8300

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